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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,654	12/12/2003	Mark T. Muldoon	19596-0562 (45738-294842)	9327

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,654	MULDOON ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 12, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

I. Claims 1-13 and 15, drawn to a method and kit for performing the method, classified in class 435, subclass 7.1.

II. Claim 14, drawn to a method of making an antibody, classified in class 435, subclass 70.1.

III. Claim 16, drawn to an antibody, classified in class 530, subclass 300.

1. Inventions I and II are independent and distinct inventions. Invention I is a method for determining the presence an analyte whereas Invention II is a method of making an antibody. Invention II requires administering to an animal a composition and Invention I does not require this limitation. Further, Invention I requires correlating the existence or nonexistence of the complex to determine presence or absence of analyte in a sample and Invention II does not require this limitation.

2. Inventions I and III are independent and distinct inventions. Invention I is a method for determining the presence an analyte whereas Invention III is an antibody selected from the antibodies designated 244C1 and 244C2. Further, the inventions are not disclosed as capable of use together.

3. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by

another and materially different process such as tissue cell culture or hybridoma technology.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Jamie Greene, Attorney on August 23, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13 and 15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14 and 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the body of the claim lacks a preamble and it is unclear what the method is directed to.

Claim 1 is vague and indefinite because it is unclear how the complex can be determined without a detectable label.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the addition of a detectable label and a wash step to remove unbound material. Because if there is no detectable label provided in claim 1, it is unclear how the complex can be determined. Further, it is unclear how one can determine the difference between bound and unbound complex without a step to separate the bound and unbound complex.

Claim 1 the recitation "for a time and under conditions" is vague and indefinite. It is unclear what time and what conditions applicant is referring to. See deficiencies throughout the claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ansfield (Production of a Sensitive Immunoassay for Detection of Ruminant Proteins in Rendered Animal Material Heated to > 130 degrees C, food & Agricultural Immunology (1994) 6, 419-433).

Ansfield discloses tests to detect bovine and ovine ruminant proteins (analyte) (p. 428). Ansfield discloses detecting the ruminant proteins in rendered animal materials (p. 428). Ansfield discloses that the extract of rendered animal material is applied to an ELISA system (p. 431). Ansfield disclose antibody (ligand) which bind to the ruminant protein (p. 422) Ansfield discloses that the ligand comprises a detectable label and that the detectable label is detected to determine the presence of the ruminant protein in the sample (p. 423). Ansfield discloses ligands coated in a location of a microtiter wells (p. 422).

10. Claims 1, 2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ansfield (US 5,910,446).

Ansfield disclose a method for assaying a rendered animal material such as bone (byproduct) for the presence, identity and/or amount of proteins (analyte) (col 3, lines14-16). Ansfield discloses detecting one or more proteins in the sample by using an immunoassay. Ansfield discloses that preferred immunoassays use a binding assay such as ELISA (col 3, lines 19-26). Ansfield discloses a double sandwich ELISA for detecting the proteins (analyte). Ansfield discloses capture antibodies coated on a

microtiter plate and labeled antibodies for generating a signal. Ansfield discloses combining the sample and reagents and detecting a signal of the labeled antibodies bound to the protein. Ansfield discloses that the sample can be meat and bone meal. Ansfield discloses that the reagents and components can be packaged into a kit (col. 3, lines 27-48).

11. Claims 1, 8, 9, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al., (Monoclonal antibodies against troponin I for the detection of rendered muscle tissues in animal feed stuffs, Meat Science (2002), 62 (4), 405-412.

Chen et al disclose a method for detecting rendered muscle tissue in animal feedstuff. Chen et al disclose the use of an ELISA immunoassay in which sample suspected of comprising an analyte is combined with antibody (ligand) and labeled ligand. Chen et al disclose measuring a signal generated and determining the presence of the analyte. Chen et al also disclose the addition of antibodies in ELISA assay that have measurably lower binding affinity for one or more different species (taxonomic groups) (p. 409-411).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1, 6-10, 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmerr et al (US 6,150,172) in view of Hamilton (Real and Perceived Issues Involving Animal Proteins, FAO presentation, Bangkok, 29th April-3rd May, 2002).

Schmerr et al disclose methods for selectively detecting protein (analyte in a sample. Schmerr et al disclose that the sample can be a biological sample or products made from animal organs or tissues such as food and processed food products, bone meal, animal fee, extracellular matrix proteins (col. 5). Schmerr et al disclose that the

detection can be performed by immunoassay such as ELISA and sandwich immunoassays (col 8-10). Schmerr et al disclose the use of antibodies (ligands) in these immunoassays. Schmerr et al disclose that the antibody can comprise a detectable label (col 9, lines 15-18). Schmerr et al disclose a kit comprising reagents and instructions (col 9, line 35 – col 10, line 29).

Schmerr et al differ from the instant invention in failing to teach the animal byproduct is rendered.

Hamiltion discloses rendering animal byproducts. Hamilton discloses that this rendering process remove the moisture and facilitates fat separation and also benefits the finished product customer. Hamilton discloses that the process kiss bacteria, viruses and many other microorganisms, to produce an aseptic protein product that is free of potential biohazards and environmental threats (p. 1).

It would have been obvious to one of ordinary skill in the art to incorporate a rendering process such as taught by Hamiltion into the method of Schmerr et al because Hamiltion teaches that the process kiss bacteria, viruses and many other microorganisms, to produce an aseptic protein product that is free of potential biohazards and environmental threats. Further, Schmerr et al teaches processing the sample before performing the method (col 5).

16. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ansfield (US 5,910,446) in view of Schuurs et al (US 3,654,090) and further in view of Deger et al (US 5,437,981).

See above for teachings of Ansfield (US 5,910,446).

Ansfield differs from the instant invention in failing to teach an analyte analog that is bound to at least one location on a solid phase, wherein the ligand has a binding affinity for the analyte analog.

Schuurs et al disclose a method for the determination of a component of the antigen-antibody reaction. Schuurs et al disclose that the test system can be composed of antigen, labeled antibody (ligand) and immobilized antigen and that the labeled antibody has binding affinity for the immobilized antigen (col 2, lines 66-69). Schuurs et al discloses that a good separation between the bound and free labeled component is essential (lines 43-44). Schuurs et al discloses that this assay format provides a method for assaying substances in very small quantities for a very high sensitivity (col 3, lines 15-18).

It would have been obvious to one or ordinary skill in the art to incorporate testing methods as taught by Schuurs et al into the method of Ansfield because Ansfield specifically teaches immunoassay such as binding assay can be used to determine the antigen of interest and further because Schuurs et al teaches that this assay format provides a method for assaying substances in very small quantities for a very high sensitivity.

Anfield and Schuurs et al fail to teach the use of an analyte analog.

Deger et al. disclose competitive immunoassays used to determine an analyte of interest (col. 1). Deger et al disclose an immobilized analog (col 1, lines57-60). Deger et al disclose combining the sample containing the ligand (analyte) and antibody (ligand) with the immobilized analog.

It would have been obvious to one or ordinary skill in the art to substitute an immobilized analog as taught by Deger et al for the immobilized antigen of the modified method of Ansfield because Deger teaches it is known in the art to use analogs as reagents in competitive immunoassays. Further, the use of analyte analog in immunoassays is very well known in the art and therefore would be considered an obvious substitution for an immobilized antigen.

17. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ansfield (US 5,910,446) in view of Jacobs et al (US 5,571,682) Guan et al (US 6,617,116)

See above for teachings of Ansfield.

Ansfield differs from the instant invention in failing to teach combining the sample and ligand with a labeled analyte analog and the ligand immobilized.

Jacobs et al disclose different types of immunoassays and teach that in competitive assay, a labeled analog of the target analyte to be determined is placed in competition with the analyte for a fixed amount of an appropriate, immobilized antibody (ligand) which can react with either the target analyte or a target analyte analog (col 1, lines 20-32). Jacobs et al disclose that this method provides for a means for determining how much target analyte is in the sample.

Guan et al disclose a competitive immunoassay for determining an analyte of interest. Guan et al disclose that analyte in sample competes with labeled analogue to the analyte, for a binding partner immobilized on a solid support (col 1, lines 37-40). Guan et al disclose that a competitive immunoassay provides a quantitative measure of analtye concentration (col 1, lines 46-48).

It would have been obvious to one of ordinary skill in the art to incorporate competitive immunoassays as taught by Jacobs et al into the method of Ansfield because Jacobs et al shows that this type of immunoassay provides for a means for determining how much target analyte is in the sample. Further, the use of competitive immunoassays using labeled analyte analogs is very well known in the art.

It also would have been obvious to one of ordinary skill in the art to incorporate competitive immunoassays as taught by Guan et al into the method of Ansfield because Guan et al shows that this type of immunoassay provides a quantitative measure of analyte concentration. Further, the use of competitive immunoassays using labeled analyte analogs is very well known in the art.

18. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmerr et al (US 6,150,172) in view of Hamilton (Real and Perceived Issues Involving Animal Proteins, FAO presentation, Bangkok, 29th April-3rd May, 2002) and further in view of Ligt et al (US 2004/0043107).

See above for teachings of Schmerr et al and Hamilton.

Schmerr et al and Hamilton differ from the instant invention in failing to teach the analyte is chondroitin sulfate.

Ligt et al disclose the presence of chondroitin sulfate in animal byproducts (paragraph 0009). Light et al discloses that the chondroitin sulfate may be in animal feeds. Ligt et al disclose the byproducts can be analyzed (example 1).

It would have been obvious to one of ordinary skill in the art to detect chondroitin sulfate with the modified method of Schmerr et al because Schmerr et al is generic with

respect to the analyte to be detected and Ligt et al teaches that it is known that animal byproducts can contain chondroitin sulfate. Thus one of ordinary skill in the art would have a reasonable expectation of success using the modified method of Schmerr et al to detect chondroitin sulfate in animal byproducts or foodstuffs.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
August 30, 2004

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